Reports of Corrections and Removals

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Reporting

What's the point?

Reporting A RISK TO HEALTH TO FDA

What Kind Of Risk? – Two Kinds

Risk #1) **Serious health outcome or death that is a reasonable probability**

e.g., toxic substance contamination in dialysis equipment

Risk #2a) A legal violation that <u>may</u> present a risk to health

e.g., implantable cardio-defibrillator software is defective, so it might not work when it should

Risk #2b) A legal violation with a remote probability of serious adverse health consequences

e.g., glucose test strip

What Kind of Report?

1) Correction

2) Removal

What Is a Correction?

- repair
- modification
- adjustment
- relabeling
- destruction
- inspection – including patient monitoring

Any of the above actions without physically removing the device from its point of use to some other location.

What Is a Removal?

The physical removal of the device from its point of use to some other location for:

- repair
- modification
- adjustment
- relabeling
- destruction
- inspection

“Corrections and Removals”

-Very Broad Concepts -

The intent is to make sure FDA knows about any risk to health associated with a Correction or Removal.

Exemptions

- Market withdrawals
- Routine servicing (scheduled or expected)
- Stock recoveries
- Performance improvements that do not:
  - reduce a risk to health,
  - correct a violation of the act.

Who Is Required to Report?

1) Manufacturers (Hospitals)
   - Domestic & Foreign

2) Initial Importers

What Information Is Reported?

1) Manufacturer (hospital) or importer registration number
2) Name, address, telephone number and contact person who is conducting correction or removal
3) Brand name and common name of device
4) 510(k) or PMA number

What Information Is Reported?

5) Model, catalog or code number
6) Responsible party (if different than # 1)
7) What happened
8) Illness or injuries
9) Total number of devices
10) Date of manufacture or distribution

Where Do You Send the Information?

To the local

FDA District Office

When Should a Report Be Submitted to FDA?

10 days after you decide a correction or removal is needed!

Reports [1] Recall Action

- A risk to health is reportable by regulation.
- Not subject to a voluntary decision to recall.

Who Is Required to Keep Records?

1) Manufacturers (Hospitals)
   - Domestic & Foreign
2) Importers
3) Distributors!

How Will FDA Know if You Did Not Report a Recall?

- Inspections
- Competitors
- Consumers
- Hospitals